



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/789,359

02/26/2004

James H. Brauker

DEXCOM.037A

5145

68851

7590

10/03/2008

KNOBBE, MARTENS, OLSEN & BEAR, LLP  
2040 MAIN STREET  
FOURTEENTH FLOOR  
IRVINE, CA 92614

EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

10/03/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/789,359	<b>Applicant(s)</b> BRAUKER ET AL.	
	<b>Examiner</b> LAURA A. BOUCHELLE	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-25,27-30,32,34,35 and 37-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25 and 37-39 is/are allowed.
- 6) ☒ Claim(s) 15-24,27-30,32,34,35 and 40-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/19/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/28/08 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 23 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 23 recites that the medicament device that is physically detachably connectable to the receiver is an implantable pump. It is unclear how a device that must be implanted by a surgeon is physically connectable to a receiver.

### ***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3763

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 29, 32, 34, 35, 42-52, 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Knobbe et al (US 6572545). Knobbe discloses a method and apparatus for treating diabetes comprising a continuous glucose sensor 108 that outputs a data stream to a receiver 114, a medicament delivery device operably connectable to the receiver, and a single point glucose monitor (CBG) configured to receive a biological sample from the hose and measure the glucose concentration in the sample (Col. 5, lines 35-45). The receiver is programmed to instruct the delivery device to deliver a treatment to the patient based on the information received from the glucose sensor. The continuous glucose sensor is calibrated on a periodic basis based on the measurements provided by the single point glucose monitor (col. 5, lines 35-65). Therefore, ultimately the amount of medicament to be delivered is calculated using the glucose concentration measured by the single point glucose monitor in combination with the glucose concentration measured by the continuous sensor. When the processor determines that the glucose values are outside a predetermined range, the single point glucose monitor is used to obtain an accurate glucose concentration (Col. 5, lines 40-45). This is considered to be a validation step as required by claim 32.

6. Knobbe discloses that the receiver includes an algorithm that estimates the real-time glucose level based on previous measurements and inputs such as exercise, food intake, insulin administration, or other factors (Col. 5, lines 46-57).

***Claim Rejections - 35 USC § 103***

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 15-24, 27, 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Say et al (US 6175752) in view of Lav et al (US 6302855). Say discloses a system for monitoring and treating diabetes comprising a glucose sensor 42 that continuously measures glucose and outputs a data stream to a receiver 46, 48, and a medicament delivery device 260 (column 54), the delivery device may be a syringe, a patch, a spray, a pen injector, or a pump (col. 54, lines 56-58).

9. Claim 15 differs from Say in calling for the delivery system to be physically detachably connectable to the receiver. Say teaches that the receiver may have a secondary device that is detachably connected to the main receiver (col. 48). Lav teaches an apparatus for treatment of diabetes comprising interconnectable devices including a body fluid analyzer and a medicament delivery device (Col. 3, lines 20-55). The body fluid analyzer corresponds to a receiver because it receives information from a glucose sensor and determines the glucose level in the patient. This promotes insulin treatment in diabetics because the devices are interconnected meaning that when a diabetic knows their glucose level the insulin delivery device is immediately at hand, and also the user can be confident that the measuring units of both devices are the same (Col. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Say to include the receiver and the delivery device as removably attached components as taught by Lav so that a user may manage diabetes with ease and confidence.

Art Unit: 3763

10. Claims 40, 41, 53, 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knobbe in view of Lav. Claims 40, 53 differ from Knobbe in calling for the single point glucose monitor to be detachably connectable to the receiver. Lav teaches an apparatus for treatment of diabetes wherein a lancet device, a body fluid analyzer and a dosing device are all interconnectably attached to enhance the convenience and ease of use of the device. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Knobbe to include a single point monitor detachably connectable to the receiver as taught by Lav.

***Allowable Subject Matter***

11. Claims 25, 37-39 are allowed.

***Response to Arguments***

12. Applicant's arguments, see pages 10-17, filed 5/28/08, with respect to the previous rejections have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Say, Knobbe, and Lav as above.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763

Laura A Bouchelle  
Examiner  
Art Unit 3763

/L. A. B./  
Examiner, Art Unit 3763  
13.